United States District Court

EASTERN DISTRICT OF TEXAS
TYLER DIVISION

ALLERGAN, INC.	**§**	
	§	
v.	**§**	**Cause No. 6:11-cv-441**
	§	
SANDOZ INC., ET AL.	**§**	

MEMORANDUM OPINION AND ORDER

On September 27, 2012, the Court held a claim construction hearing to construe disputed terms. Since then, additional patents have issued which the parties agreed to consolidate into this litigation. The Court granted the parties' request to construe additional terms. Accordingly, this order addresses the disputed claim terms of U.S. Patent Nos. 8,278,353 ('353 patent) and 8,299,118 ('118 patent).[1] Defendants primarily argue that the asserted claims of the '353 and '118 patents are invalid for indefiniteness. For the following reasons, the Court adopts the constructions set forth below and **DENIES** Defendants' motion for indefiniteness.

I. BACKGROUND

This is a patent infringement action filed pursuant to the Hatch-Waxman Act. Plaintiff Allergan, Inc. obtained FDA approval for Lumigan® 0.03% bimatoprost ophthalmic solution in 2001. In late 2010, Plaintiff obtained FDA approval for Lumigan® 0.01% bimatoprost ophthalmic solution for the reduction of elevated intraocular pressure in certain patients, including those with open angle glaucoma or ocular hypertension. The active ingredient in

[1] As part of their Joint Claim Construction and Prehearing Statement, the parties attached a chart indicating their disputed claim terms (Doc. No. 156-1). The parties indicate disagreement regarding the construction of "citric acid buffer" in claims 6 and 8 of U.S. Patent No. 8,309,605. But in the parties' subsequent briefing, they assert that the claim construction issues before the Court are limited to the '353 and '118 patents (Doc. No. 167 at 4). Based upon this assertion and because none of the parties addressed this claim phrase in their briefing, the Court assumes the parties have resolved their dispute over this phrase. Thus, the Court refrains from addressing its construction.

Lumigan® is the prostaglandin analog bimatoprost, which operates by increasing the outflow of aqueous humor from the eye.

Defendants have each filed an Abbreviated New Drug Application (ANDA) for FDA approval to market a generic version of Plaintiff's Lumigan® 0.01% bimatoprost ophthalmic solution. Defendants seek to market their generic versions prior to the expiration of the patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication (known as the Orange Book) as covering Plaintiff's Lumigan® 0.01% bimatoprost ophthalmic solution.

For purposes of this order, all of the disputed claim terms arise from the '353 and '118 patents. The '353 patent is directed to a composition, while the '118 patent is directed to a method of using that composition. The disputed terms appear in both patents. Furthermore, the patents share identical specifications and derive from the same parent application.

Independent claim 1 of the '353 patent is representative of the composition claims:

> A first composition administered once daily for lowering intraocular pressure in a person with glaucoma or ocular hypertension, the first composition comprising about 0.01% w/v bimatoprost and about 0.02% w/v benzalkonium chloride, wherein the first composition lowers intraocular pressure and results in less hyperemia as compared to the once daily administration of a second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride.

'353 Patent at 5:48–56.

Independent claim 1 of the '118 patent is representative of the method claims:

> A method of lowering intraocular pressure in a person with glaucoma or ocular hypertension, the method comprising administering once daily to an eye of the person a first composition comprising about 0.01% w/v bimatoprost and about 0.02% w/v benzalkonium chloride, wherein the method lowers intraocular pressure and results in less hyperemia as compared to the once

> daily administration of a second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride.

'118 Patent at 5:48–56.

II. LEGAL STANDARD

A. Claim Construction

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). The purpose of claim construction is to resolve the meanings and technical scope of claim terms. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). When the parties dispute the scope of a claim term, "it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The claims of a patent define the scope of the invention. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). They provide the "metes and bounds" of the patentee's right to exclude. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Accordingly, claim construction begins with and "remain[s] centered on the claim language itself." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

Claim terms are normally given their "ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Generally, "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id* at 1313.

The best guide for defining a disputed term is a patent's intrinsic evidence. *Teleflex*, 299 F.3d at 1325. Intrinsic evidence includes the patent's specification and the prosecution history. *Id.*

The claims are part of the specification. *Markman*, 52 F.3d at 979. ."). "[T]he context in which a term is used in the asserted claim can be highly instructive." *Phillips,* 415 F.3d at 1314; *see also Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed Cir. 1997) ("[T]he language of the claim frames and ultimately resolves all issues of claim interpretation."). "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314.

In addition to the claims, the specification's written description is an important consideration during the claim construction process. *See Vitronics Corp.*, 90 F.3d at 1582. The written description provides further context for claim terms and may reflect a patentee's intent to limit the scope of the claims. *See Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582).

The specification may also resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex, Inc.*, 299 F.3d at 1325. For example, "[a] claim interpretation that excludes a preferred embodiment from the scope of the claim 'is rarely, if ever, correct.'" *Globetrotter Software, Inc. v. Elam Computer Grp., Inc.*, 362 F.3d 1367, 1381 (Fed. Cir. 2004) (quoting *Vitronics Corp.*, 90 F.3d at 1583).

But care must be taken to avoid unnecessarily reading limitations from the specification into the claims. *Teleflex*, 299 F.3d at 1326; *see also Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983) ("That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims."). "[P]articular

embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water*, 381 F.3d at 1117; *see also Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

The prosecution history is also part of the intrinsic evidence. *Phillips*, 415 F.3d at 1317. It "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Id.* "As in the case of the specification, a patent applicant may define a term in prosecuting a patent." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004). Statements made during the prosecution of the patent may limit the scope of the claims. *Teleflex*, 299 F.3d at 1326; *see Omega Eng'g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (explaining that the doctrine of prosecution disclaimer "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution").

Finally, the Court may rely on extrinsic evidence to aid with understanding the meaning of claim terms. *Markman*, 52 F.3d at 981. Extrinsic evidence includes "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* at 980. Extrinsic evidence is generally less useful or reliable, *Phillips*, 415 F.3d at 1317, and it should not be relied on when it contradicts the intrinsic evidence, *Markman*, 52 F.3d at 981.

B. Claim Indefiniteness

Patent claims must particularly point out and distinctly claim the subject matter regarded as the invention. 35 U.S.C. § 112, ¶ 2. Whether a claim meets this definiteness requirement is a

matter of law. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir. 2007). A party challenging the definiteness of a claim must show it is invalid by clear and convincing evidence. *Id.* at 1345.

"Only claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250 (Fed. Cir. 2008) (quoting *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005)). The ultimate issue is whether someone working in the relevant technical field could understand the bounds of a claim. *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010).

III. DISCUSSION

The parties' dispute focuses on the meaning and scope of one phrase in the claims of the patents. The remainder of the parties' disagreement is based upon claim indefiniteness.

A. "[W]ithout a substantial reduction in the intraocular pressure lowering benefit"[2]

Disputed Claim Phrase	Plaintiff's Proposed Construction	Defendant Sandoz Inc.'s Proposed Construction
"[W]ithout a substantial reduction in the intraocular pressure lowering benefit"	"[W]ith at least approximately or nearly equivalent intraocular pressure lowering benefit"	"[W]ith approximately or nearly equivalent intraocular pressure lowering benefit"

The parties' dispute on this phrase concentrates on the definition of "substantial." Plaintiff and Sandoz both propose similar constructions, while the remaining Defendants contend the term is indefinite.

Regarding indefiniteness, Defendants argue that the term "substantial" calls for an evaluation of degree. Defendants allege that the specifications do not provide guidance to determine when reduced intraocular pressure qualifies as "substantial." Defendants conclude this renders the claim indefinite.

[2] The phase "without a substantial reduction in the intraocular pressure lowering benefit" is found in claim 7 of both the '353 and '118 patents.

Plaintiff responds that use of "substantial" reasonably conveys the claimed subject matter to one of ordinary skill in the art. Plaintiff cites a number of cases where courts have found claim terms referencing degree, including "substantial," are not inherently indefinite. Plaintiff also argues that terms not defined in the specification are not indefinite if a person of ordinary skill in the art would understand their meaning. Furthermore, Plaintiff asserts that the file history establishes that one of ordinary skill in the art would appreciate how to compare intraocular pressure lowering between 0.01% and 0.03% bimatoprost ophthalmic solutions.

Defendants do not address or distinguish any of the cases cited by Plaintiff. *See, e.g.*, *Reedhycalog UK, Ltd. v. Baker Hughes Oilfield Operations, Inc.*, No. 6:06-CV-222, 2007 WL 3001423, at *4 (E.D. Tex. Oct. 12, 2007) (explaining that "[a] lay jury will understand what 'substantially' means, and therefore the term does not require construction"). The Federal Circuit "has repeatedly confirmed that relative terms such as 'substantially' do not render patent claims so unclear as to prevent a person of skill in the art of from ascertaining the scope of the claim." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1359 (Fed. Cir. 2012). The Court finds this same principal applicable here. In this case, the phrase "substantial reduction" would not be unclear to a person of ordinary skill in the art at the time of filing.

Defendants also challenge Plaintiff's reliance on the intrinsic record to establish meaning for the claim phrase. Specifically, Defendants challenge Plaintiff's reliance on the file history. Defendants argue that that the documents relied upon by Plaintiff discuss clinical testing that occurred after the effective filing date of the asserted patents. Defendants conclude this data is irrelevant because indefiniteness is determined from the perspective of a person of ordinary skill in the art at the time of the patent application. *See Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1372 (Fed. Cir. 2005).

Defendants correctly note that "the literal scope of the term is limited to what it was understood to mean at the time of filing." *Kopykake Enters., Inc. v. Lucks Co.*, 264 F.3d 1377, 1383 (Fed. Cir. 2001). But documents or data arising after the filing of an application can still be probative to assess the scope of a term at the time of filing. *See Howmedica*, 401 F.3d at 1372 (finding that "references to the 'cross-sectional area' in the discussion between the examiner and the applicant at a later time are relevant to the meaning of 'traverse sectional dimensions' to one of skill in the art at the earlier time of filing"). In this case, Plaintiff's post-filing intrinsic evidence contains studies comparing the efficacy of lowering intraocular pressure for 0.01% and 0.03% bimatoprost ophthalmic solutions. The Court finds these studies accurately reflect that one of ordinary skill in the art at the time of filing would appreciate the meaning of "substantial" and how to compare the efficacy of the two solutions.

Turning to construction, Plaintiff and Sandoz generally agree on the same construction. But the Court finds both constructions unnecessarily redundant. Accordingly, the Court construes "without a substantial reduction in the intraocular pressure lowering benefit" to mean "with nearly equivalent intraocular pressure lowering benefit."

B. "[A] second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride"[3]

Defendants also assert that the language "a second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride" in claim 7 of the patents is indefinite. Defendants allege that the use of the open-ended term "comprising" to define "second composition" allows for additional undisclosed ingredients. Defendants maintain that the specifications do not address what additional ingredients might be included or how it would affect the efficacy comparison. Plaintiff contends that Defendants' "comprising" argument is

[3] The phrase "a second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride" is found in claim 7 of both the '353 and '118 patents.

misplaced because the phrase "second composition comprising" is immediately preceded by the indefinite article "a." Under the relevant law, "a" is generally understood to mean "one or more." *See Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338 (Fed. Cir. 2008) ("That 'a' or 'an' can mean 'one or more' is best described as a rule, rather than merely as a presumption or even a convention."). Thus, Plaintiff maintains that one of ordinary skill in the art would understand that the claim is infringed only where the second composition shows comparable results to at least one 0.03% bimatoprost formulation. The Court agrees. One of ordinary skill in the art would not understand the claim to require the second composition to have comparable efficacy to every single variation, rather, to just one 0.03% bimatoprost formulation. Accordingly, the Court does not find the claim language insolubly ambiguous or indefinite.

C. "[A]s compared to . . . [a/the] second composition"[4]

Defendants, excluding Sandoz, argue that the phrase "as compared to . . . [a/the] second composition" is indefinite. Defendants again assert that the specifications provide no guidance for comparing a "first composition" to a "second composition." Defendants state that to conduct comparative clinical assessments the specifications must provide substantial guidance. The Court does not find the claim phrase indefinite. In light of the intrinsic and extrinsic evidence, this phase is not insolubly ambiguous.

As previously noted, the file history of the '353 and '118 patents provides clear context of the required comparison. Furthermore, the data and studies in the file history establish that one of ordinary skill in the art at the time of filing would appreciate the appropriate parameters for a comparative clinical study in this field.

[4] The phrase "as compared to . . . [a/the] second composition" is found in claims 1, 8, 15, 16, 23, and 25 of the '353 and '118 patents.

Plaintiff additionally notes that the extrinsic evidence gives abundant guidance on how to conduct the comparison. In particular, Plaintiff identifies the prior art listed on the face of the '353 and '118 patents as containing numerous studies comparing glaucoma treatments.

Based upon the intrinsic and extrinsic evidence, the Court does not find the claim phrase "as compared to . . . [a/the] second composition" indefinite. Furthermore, the Court finds that the phase is entitled to its plain and ordinary meaning.

D. "[L]ess hyperemia"[5]

Defendants, excluding Sandoz, allege that the phase "less hyperemia" is indefinite. According to Defendants, the specifications contain no description to allow one of ordinary skill in the art to determine what degree of reduction qualifies as "less."

Defendants already have agreed to a proposed construction of "less hyperemia." As part of their Joint Claim Construction and Prehearing Statement (Doc. No. 156), Defendants agree that "less hyperemia" means "hyperemia in fewer patients or the level of hyperemia is lower in some patients (or both)." Therefore, Defendants' indefiniteness argument is substantially undercut by their agreed joint construction. *See Versata Software, Inc. v. SAP AM., Inc.*, No. 2:07-CV-153, 2009 WL 1408520, at *10 n.3 (E.D. Tex. May 19, 2003) (explaining that although not dispositive on the issue, "[a] party's proposed construction of a disputed term in its P.R. 4–3 disclosures supports the conclusion that a disputed term is not indefinite"); *Power-One, Inc. v. Artesyn Techs., Inc.*, No. 2:05-CV-463, 2007 WL 896093, at *5 n.3 (E.D. Tex. Mar. 22, 2007) (finding the defendant's proposed construction of a term indicated that the term was amendable to construction and therefore not indefinite).

Regardless, as reflected in the intrinsic record, one of ordinary skill in the art would understand the scope of this claim phrase. The studies and data in the file history provide precise

[5] The phrase "less hyperemia" is found in claims 1, 8, 16, and 25 of the '353 and '118 patents.

details on how the level of eye redness, or hyperemia, can be assessed. Specifically, the studies instruct that a change in hyperemia is graded on a five-point scale and that changes in severity from a baseline fall within three categories. Although this material arose after the effective filing date, it remains a useful guide in determine what one of skill in the art understood at the time of filing. The Court finds that one of skill in the art would have understood how to compare changes in hyperemia at the time of the effective filing date.

The extrinsic evidence is consistent with the Court's finding. Plaintiff cites to a pre-filing date article that discusses a hyperemia study. The study implements the identical five-point scale used by Plaintiff. This further supports Plaintiff's assertion that one of ordinary skill in the art would understand how to characterize and compare hyperemia.

Based upon the intrinsic and extrinsic evidence, the Court does not find the claim phrase "less hyperemia" indefinite. Furthermore, the Court finds that the phase is entitled to its plain and ordinary meaning.

E. "[W]herein the first composition remains useful in treating glaucoma or ocular hypertension despite a lower concentration of bimatoprost"[6]

Excluding Sandoz, Defendants argue that the claim phrase "wherein the first composition remains useful in treating glaucoma or ocular hypertension despite a lower concentration of bimatoprost" is indefinite. Defendants assert the specifications do not provide any guidance for determining when a particular formulation "remains useful."

Although Defendants now argue indefiniteness, Defendants initially proposed a construction for this phrase. This significantly weighs against a finding that one of skill in the art would find the phrase's scope irreconcilably unclear. *Versata*, 2009 WL 1408520, at *10 n.3; *Power-One*, 2007 WL 896093, at *5 n.3.

[6] The phrase "wherein the first composition remains useful in treating glaucoma or ocular hypertension despite a lower concentration of bimatoprost" is found in claims 15 and 24 of the '353 and '118 patents.

Furthermore, Plaintiff notes that the clinical trials in the file history demonstrate that the phrase requires the 0.01% bimatoprost formulation to have comparable efficacy to the 0.03% bimatoprost solution. The clinical trials indicate that an infringing formulation would be "equivalen[t] in efficacy" and have "significantly fewer ocular adverse events and significantly fewer discontinuations due to ocular adverse events" as compared to the 0.03% bimatoprost formulation (Doc. No. 160-17 at 42). Based upon the intrinsic evidence, the Court finds that one of ordinary skill in the art at the time of filing would understand the scope of the phrase "remains useful."

The Court does not find the phrase "wherein the first composition remains useful in treating glaucoma or ocular hypertension despite a lower concentration of bimatoprost" to be indefinite. Moreover, the Court finds that this phrase is entitled to its plain and ordinary meaning.

F. "[E]ffective in treating [glaucoma/ocular hypertension]"[7]

Lastly, Defendants argue the term "effective" is indefinite because the specification provides no standard for its determination. Sandoz again refrains from joining in the remaining Defendants' argument.

Defendants allege that without any guidance, it is impossible for one of ordinary skill in the art to determine when the claim is infringed. The Court again finds Defendants' argument unpersuasive.

As an initial matter, Defendants use the term "effective" as part of the definition for another claim phrase in claim 15 of the patents. Defendants' use of this disputed term in a proposed construction counsels against indefiniteness. Additionally, a person of ordinary skill in the art at the time of filing would understand how to determine the effectiveness of glaucoma or

[7] The phrase "effective in treating [glaucoma/ocular hypertension" is found in claims 5, 6, 13, 14, 20, 22, 26, and 27 of the '353 and '118 patents.

ocular hypertension treatments. One of ordinary skill in the art would be well versed in advising on these ocular treatments and subsequently determining their effectiveness. As previously discussed, the Court finds that the intrinsic and extrinsic evidence demonstrates that one of skill in the art would understand how to determine the clinical effectiveness of various treatments.

The Court does not find the phrase "effective in treating [glaucoma/ocular hypertension]" to be indefinite. Rather, the Court finds this phrase entitled to its plain and ordinary meaning.

IV. CONCLUSION

For the foregoing reasons, the Court adopts the constructions as set forth above and those listed in the attached chart. Furthermore, Defendants' motion regarding indefiniteness is **DENIED**.

It is SO ORDERED.

SIGNED this 27th day of March, 2013.

MICHAEL H. SCHNEIDER
UNITED STATES DISTRICT JUDGE

APPENDIX A[8]

Claim Term	Location	Court's Construction
"a composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid"	'504 Patent, Claims 2 & 3	"a composition that is an aqueous liquid in which citric acid monohydrate is one of the materials that is used to prepare the composition"
"about 0.014 citric acid monohydrate"	'504 Patent, Claim 3	"approximately 0.014% weight/volume citric acid monohydrate."
"phosphate buffer"	'504 Patent, Claims 1–3	**[Agreed]** No construction
"about 0.01% bimatoprost"	'504 Patent, Claims 1–3	**[Agreed]** "approximately 0.01% bimatoprost"
"pH of about 7.3"	'504 Patent, Claims 1–3	**[Agreed]** "pH of approximately 7.3"
"about 200 ppm benzalkonium chloride"	'504 Patent, Claims 1 & 2	**[Agreed]** "approximately 200 ppm benzalkonium chloride"
"said composition is an aqueous liquid which is formulated for ophthalmic administration"	'504 Patent, Claims 1–3	**[Agreed]** "said composition is an aqueous liquid that is formulated such that it can be administered topically to the eye"
"buffer"	'479 Patent, Claim 1	**[Agreed]** "an ingredient used to adjust the pH or to maintain the pH in a desirable range"
"buffering agent"	'353 Patent, Claims 4, 11, & 29; '118 Patent, Claims 4, 12, & 29; '605 Patent, Claims 12 & 18	**[Agreed]** "an ingredient used to adjust the pH or to maintain the pH in a desirable range"
"about 0.26% w/v sodium phosphate dibasic"	'479 Patent, Claim 13	**[Agreed]** "approximately 0.26% w/v sodium phosphate dibasic"
"about 0.8% w/v sodium chloride"	'479 Patent, Claim 15 & 16	**[Agreed]** "approximately 0.8% w/v sodium chloride"

[8] All other terms and phrases in the asserted claims are to be given their plain and ordinary meaning as they would be understood by a person of ordinary skill in the art.

"about 0.26% w/v sodium phosphate dibasic heptahydrate"	'479 Patent, Claim 15	**[Agreed]** "approximately 0.26% w/v sodium phosphate dibasic heptahydrate"
"the first composition lowers intraocular pressure and results in less hyperemia as compared to the once daily administration of a second composition"	'353 Patent, Claim 1	**[Agreed]** "the first composition lowers intraocular pressure, and results in hyperemia in fewer patients or the level of hyperemia observed is lower in some patients (or both) as compared to the once daily administration of a second composition"
"the method lowers intraocular pressure and results in less hyperemia as compared to the once daily administration of a second composition"	'118 Patent, Claim 1	**[Agreed]** "the method lowers intraocular pressure, and results in hyperemia in fewer patients or the level of hyperemia observed is lower in some patients (or both) as compared to the once daily administration of a second composition"
"without a substantial reduction in the intraocular pressure lowering benefit"	'353 Patent, Claim 7; '118 Patent, Claim 7	"with nearly equivalent intraocular pressure lowering benefit"
"the once daily administration of the first composition results in less hyperemia as compared to the once daily administration of the second composition"	'353 Patent, Claims 8 & 16; '118 Patent, Claims 8, 16, & 25	**[Agreed]** "the once daily administration of the first composition results in hyperemia in fewer patients or the level of hyperemia observed is lower in some patients (or both) as compared to the once daily administration of the second composition"
"the first composition results in less hyperemia as compared to the once daily administration of the second composition"	'353 Patent, Claim 25	**[Agreed]** "the first composition results in hyperemia in fewer patients or the level of hyperemia observed is lower in some patients (or both) as compared to the once daily administration of the second composition"